

BIJSLUITER: INFORMATIE VOOR DE GEBRUIKER

Deslorasam 5 mg filmomhulde tabletten Desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Deslorasam is and what it is used for
2. What you need to know before you take Deslorasam
3. How to take Deslorasam
4. Possible side effects
5. How to store Deslorasam
6. Contents of the pack and other information

1. What Deslorasam is and what it is used for

What Deslorasam is

Deslorasam contains desloratadine which is an antihistamine.

How Deslorasam works

Deslorasam is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Deslorasam should be used

Deslorasam relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Deslorasam is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take Deslorasam

Do not take Deslorasam

- if you are allergic to desloratadine or any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Deslorasam:

- if you have poor kidney function.
- if you have medical or familial history of seizures.

Use in children and adolescents

Do not give this medicine to children less than 12 years of age.

Other medicines and Deslorasam

There are no known interactions of Deslorasam with other medicines. Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Deslorasam with food, drink and alcohol

Deslorasam may be taken with or without a meal.
Use caution when taking Deslorasam with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Taking Deslorasam is not recommended if you are pregnant or nursing a baby.

Fertility

There is no data available on male/female fertility.

Driving and using machines

At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

Deslorasam contains lactose.

Deslorasam film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Deslorasam

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents 12 years of age and over

The recommended dose is one tablet once a day with water, with or without food.

This medicine is for oral use.

Swallow the tablet whole.

Regarding the duration of treatment, your doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Deslorasam.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.

If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your doctor may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your doctor.

If you take more Deslorasam than you should

Take Deslorasam only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Deslorasam than you were told to tell your doctor or pharmacist immediately.

If you forget to take Deslorasam

If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Deslorasam

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During the marketing of Deslorasam, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

In clinical studies with Deslorasam, the following side effects were reported as:

Common: the following may affect up to 1 in 10 people

- fatigue
- dry mouth
- headache

Adults

During the marketing of Deslorasam, the following side effects were reported as:

Very rare: the following may affect up to 1 in 10,000 people

- | | | |
|---|----------------------|-----------------------------------|
| ● severe allergic reactions | ● rash | ● pounding or irregular heartbeat |
| ● fast heartbeat | ● stomach ache | ● feeling sick (nausea) |
| ● vomiting | ● upset stomach | ● diarrhoea |
| ● dizziness | ● drowsiness | ● inability to sleep |
| ● muscle pain | ● hallucinations | ● seizures |
| ● restlessness with increased body movement | ● liver inflammation | ● abnormal liver function tests |

Not known: frequency cannot be estimated from the available data

- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased
- increased appetite

Children

Not known: frequency cannot be estimated from the available data

- slow heartbeat
- changes in the way the heart beats
- abnormal behaviour
- aggression

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Deslorasam

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Do not use this medicine if you notice any change in the appearance of the tablets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Deslorasam contains

- The active substance is desloratadine. Each film-coated tablet contains 5 mg desloratadine.
- The other ingredients are:
 - Tablet core:
poloxamer type 188, citric acid monohydrate, microcrystalline cellulose, maize starch, croscarmellose sodium, lactose monohydrate, talc.
 - Tablet coat:
polyvinyl alcohol (part. hydrolyzed), titanium dioxide (E 171), macrogol/peg 3350 and indigo carmine aluminium lake (E 132), talc.

What Deslorasam looks like and contents of the pack

Deslorasam are round, biconvex, blue film-coated tablets with a diameter of 6.5 mm.

The product is supplied in packs of 7, 10, 14, 15, 20, 30, 40, 50, 60, 90 and 100 film-coated tablets. Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

Archie Samuel s.r.o.

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Tsjechië

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Duitsland

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31-546 Krakow

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In het register ingeschreven onder

RVG 109600

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Duitsland: Desloratadin AbZ 5 mg Filmtabletten

Nederland: Deslorasam 5 mg filmomhulde tabletten

Deze bijsluiter is voor het laatst goedgekeurd in maand december 2017